K071711

6.0 510(k) SUMMARY OF THE *ASCA-CHEK* TEST

Contact Information

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Date Prepared July 23, 2007

Product and Trade Name *ASCA-CHEK*

NOV 0 7 2007

Classification Class II, 21 CFR 866.5785

Predicate Devices

- QUANTA Lite™ ASCA IgG (K000732). An ELISA for the semi-quantitative detection of anti-*Saccharomyces cerevisiae* IgG antibodies (ASCA) in human serum as an aid for the differential diagnosis of Crohn's disease from ulcerative colitis.
- QUANTA Lite™ ASCA IgA (K000733). An ELISA for the semi-quantitative detection of anti-*Saccharomyces cerevisiae* IgA antibodies (ASCA) in human serum as an aid for the differential diagnosis of Crohn's disease from ulcerative colitis.

Intended Use

The *ASCA-CHEK* test is an enzyme-linked immunosorbent assay (ELISA) for the qualitative detection of human anti-*S. cerevisiae* antibodies (ASCA) in feces and **serum**. The test result is used as an aid in the diagnosis of Crohn's disease in combination with clinical and other laboratory findings.
FOR *IN VITRO* DIAGNOSTIC USE.

Device Description

The *ASCA-CHEK* test is an ELISA for the measurement of human anti-*S. cerevisiae* antibodies in feces and **serum** as an indicator of Crohn's disease in combination with other clinical and laboratory findings. The assay utilizes antigens of *S. cerevisiae* for capture and a polyvalent anti-human immunoglobulin conjugate. For feces, a specimen dilution of 1:10 and an OD_{450} cut-off ≥0.150 or $OD_{450/620}$ ≥0.110 are used for the analysis. For **serum**, a specimen dilution of 1:1000 and an OD_{450} cut-off ≥0.110 or $OD_{450/620}$ ≥0.080 are used for the analysis. When human ASCA is present in fecal or **serum** specimens, the specific immunoglobulins bind to the *S. cerevisiae* antigens that are immobilized in the test well. Following this binding step, the polyvalent anti-human horseradish peroxidase (HRP) conjugate binds to the ASCA and reacts with the substrate to produce a positive result. The measurement of fecal and serum ASCA is an indicator of Crohn's disease within the setting of differentiating Crohn's disease from

ulcerative colitis and IBS. This diagnostic method offers a simple to perform assay that may be used with either fecal or serum specimens.

Comparative information of equivalent devices

Test	Description	Format	Turn-around time	Limitations
ASCA-CHEK (Fecal and Serum ASCA: K071711)	Intended for determining the presence of Ig antibodies against *S. cerevisiae* (ASCA antibodies) in **fecal and serum specimens of adult and pediatric patients** as an aid in the diagnosis of Crohn's disease.	ELISA (multi-step)	75 minutes	ASCA are found in about 50 to 60% of persons with Crohn's disease. The two-step ELISA procedure requires multiple wash steps. The test does not identify all persons with Crohn's disease.
QUANTA Lite™ ASCA (*S. cerevisiae*) IgG ELISA (K000732)	Intended for determining the presence of IgG antibodies against *S. cerevisiae* (ASCA antibodies) in **serum of adult patients**	ELISA (multi-step)	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.
QUANTA Lite™ ASCA (*S. cerevisiae*) IgA ELISA (K000733)	Intended for determining the presence of IgA antibodies against *S. cerevisiae* (ASCA antibodies) in **serum of adult patients**	ELISA (multi-step)	90 minutes	ASCA serum antibodies are found in about 50 to 60% of persons with Crohn's disease. The test does not identify all persons with Crohn's disease.

Summary of Performance Data

Combined Analysis for Pediatric and Adult Patients plus Healthy Controls

Site: Pediatric Patients plus Controls	N=	Sensitivity or Positive Percent Agreement	Specificity or Negative Percent Agreement	Agreement or Overall Percent Agreement
ASCA-CHEK vs Disease	136	60%	86%	68%
QUANTA Lite™ ASCA vs Disease	136	58%	95%	70%
ASCA-CHEK vs QUANTA Lite™ ASCA	136	82%*	80%*	81%*
Site: Adult Patients plus Controls				
ASCA-CHEK vs Disease	215	65%	95%	84%
QUANTA Lite™ ASCA vs Disease	138	75%	96%	88%
ASCA-CHEK vs QUANTA Lite™ ASCA	138	78%*	94%*	89%*
Site: All Patients plus Controls				
ASCA-CHEK vs Disease	351	62%	93%	78%
QUANTA Lite™ ASCA vs Disease	274	64%	95%	79%
ASCA-CHEK vs QUANTA Lite™ ASCA	274	80%*	88%*	85%*

***Reference guidance document entitled "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic".**

Based on these findings, we believe the *ASCA-CHEK* test is substantially equivalent to other diagnostic tests now used to evaluate patients suspected of having inflammatory bowel disease. Further, our results demonstrate that the *ASCA-CHEK* test is suitable for use with both fecal and **serum** specimens as an *in vitro* diagnostic aid to help identify patients with Crohn's disease in combination with other clinical and laboratory findings when assessing patients with chronic intestinal illnesses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Director of Product Development
2001 Kraft Drive
Blacksburg, VA 24060-6358

NOV 07 2007

Re: k071711
Trade/Device Name: ASCA-CHEK
Regulation Number: 21 CFR 866.5785
Regulation Name: Anti-*Saccharomyces Cerevisiae* (ASCA) test system
Regulatory Class: Class II
Product Code: NBT
Dated: July 23, 2007
Received: October 25, 2007

Dear Mr. Pennington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K071711

Device Name: *ASCA-CHEK*

Indications For Use:

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FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K071711